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10/647,657	08/25/2003	William Cohn	301492.1047-119	2131

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EXAMINER	
BACHMAN, LINDSEY MICHELE	
ART UNIT	PAPER NUMBER
3734	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/647,657	COHN ET AL.	
	Examiner	Art Unit	
	Lindsey Bachman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-26-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on 26 April 2007.

Terminal Disclaimer

1. The terminal disclaimer filed on 26 April 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of United States Patent 6,610,071 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Information Disclosure Statement

2. The information disclosure statement filed 22 January 2004 and 26 April 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed, specifically WO 98/53745 and WO 99/60929 and EP 0 554 653. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4, 16, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965 in view of Soviet Union Patent 513696 (SU'696).

4. Claim 1-4, 20: Phillips'965 teaches a method of implanting an artificial valve including placing a first suture (26) though tissue (40) at a first position using a first needle (32); placing a second needle (34) through tissue (40) at a second position, and repeating this processes using additional needles. The prosthetic device (16) is attached to the annulus body tissue (40) using needles in the suturing system and is then secured to the body (column 2, lines 15-46). Phillips'965 teaches color-coding to identify different threads (column 1, lines 23-57 and column 2, lines 40-44). Phillips'965 does not explicitly teach color-coding different sutures attached to the same needle. Phillips does not teach using a suture system that contains at least three needles connected by suture strands.

5. SU'696 teaches suture system that contains three needles (2) connected by sutures (5, 6,7, 8) that are spread apart by a pre-determined length of suture. SU'696 teaches that it is well-known to use a system like this when attaching two biomaterials

(shown in figure, but unlabeled) because it reduces the time needed to apply several stitches because there are fewer needle insertions and it makes the joint created with the sutures stronger because there are no sectors between the adjacent knot stitches (Derwent abstract). It would have been obvious one of ordinary skill in the art to substitute the suture/needle combination taught by Phillips'965 with the suture system taught by SU'696 because the results of the substitution would have been predicable and superior to the system taught by Phillips since the system taught by SU'696 is faster to use and creates stronger joints.

6. Phillips'965 in view of SU'696 contains a base device (the suture system) upon which the claimed invention is an improvement (different colored threads attached to one needle). Phillips'965 in view of SU'696 is a comparable device that was improved in the same way as Applicant's invention (both Phillips'965 in view of SU'696 and Applicant are claiming color coding threads in a suture system). It would have been obvious to one of ordinary skill in the art to apply the known improvement technique (color-coding) in the same way depending on the threads being tied together to the base device taught by SU'696 and Phillips and the results would have been entirely predictable. See *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 and *KSR International Co. v. Teleflex, Inc.*, 550 U.S.—, 82 USPQ2d 1385 (2007).

7. Claim 16: Phillips'965 teaches passing sutures through both the cuff (18) and the valve (12).

8. Claim 17: Philips'965 teaches the method substantially as claimed, except for passing different strands attached to the same needle through the same hole in the

tissue. SU'696 teaches passing different suture strands attached to the same needle through the same hole because it reduces the time needed to apply several stitches because there are fewer needle insertions and it makes the joint created with the sutures stronger because there are no sectors between the adjacent knot stitches (Derwent abstract). It would have been obvious one of ordinary skill in the art to substitute the suture/needle combination taught by Phillips'965 with the suture system taught by SU'696 because the results of the substitution would have been predicable and superior to the system taught by Phillips since the system taught by SU'696 is faster to use and creates stronger joints.

9. Claim 18: Phillips'965 teaches attaching a valve (column 1, lines 5-20).

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips'965 and SU'696, as applied to Claim 1, and in further view of Ablaza (US Patent 4,632,113).

11. Phillips'965 and SU'696 and teach the limitations of Claim 15, except for the use of suture pads.

12. Ablaza'113 teaches the use of suture pads (12 in Figure 1, or 20 in Figure 2) attached to suture strands (18) because they prevent any movement between the suture and the pad, and reduce the tendency of the suture to tangle; further, Ablaza'113 teaches that suture pads are used as anchors when the suturing device is used to close a slit in an aorta (column 2, lines 63-68 and column 3, lines 1-8). Therefore it would have been obvious to one skilled in the art at the time the invention was made to modify

the device taught by Phillips'965 and SU'696 with a suture pad because they allow the suture to act as an anchor when closing the aorta.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965 and SU'696, as applied to Claim 1, and in further view of Alpern, et al. (US Patent 5,284,293).

14. Phillips'965 and SU'696 teach the limitations of Claim 19, except for the use of a package for housing the suture device. Alpern'293 teaches that it is well known in the art to use a dispenser to house suturing devices prior to use because they are packaged in a sterile manner and it is beneficial to be able to see the quantity of suturing devices in a box (column 1, lines 1-34). Therefore it would have been obvious to one skilled in the art at the time the invention was made to place sterile packaged sutures taught by Phillips'965 and SU'696 in a box, as taught by Alpern'293, prior to use because this makes it easier for doctors to see the quantity of suturing devices in the box.

15. Claim 5, 6, 7, 8, 10, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soviet Union Patent 513696 (SU'696) in further view of Phillips (US Patent 4,932,965).

16. Claims 5, 6 and 8: SU'696 teaches a suturing device containing at least three needles (2) with at least one needle being attached to a double stranded suture (6, 7); each suture strand extends between a pair of connected needles. The needles (2) are removable from the suture strands (Derwent Abstract, line 5). SU'696 does not teach the use of a visual indicator to identify the individual suture strands.

17. Phillips'965 teaches the use of a valve sewing ring containing pairs of sutures with needles attached in which each suture pair is color coded between with two different colors to aid in identification of the individual sutures (column 1, lines 23-42). Regarding color-coding, SU'696 in view of Phillips contains a base device (the suture system) upon which the claimed invention is an improvement (different colored threads attached to one needle). SU'696 in view of Phillips is a comparable device that was improved in the same way as Applicant's invention (both SU'696 in view of Phillips and Applicant are claiming color coding threads in a suture system). It would have been obvious to one of ordinary skill in the art to apply the known improvement technique (color-coding) in the same way, depending on the threads being tied together, to the base device taught by SU'696 and Phillips and the results would have been entirely predictable. See *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 and *KSR International Co. v. Teleflex, Inc.*, 550 U.S.—, 82 USPQ2d 1385 (2007).

18. Claim 7: SU'696 teaches that suturing device contains three needles (2) that are associated with at least two sutures strands (5, 6, 7, 8).

19. Claims 10, 11, and 14: Phillips'965 teaches a cuff (16) through which sutures (26) are threaded (column 2, lines 16-32) during aortic valve replacement surgery (column 1, lines 1-20). The cuff is threaded before surgery to reduce implantation time (column 1, lines 23-42). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use the device taught by SU'696 and Phillips'965 to suture a cuff prior to surgery in order to reduce implantation time and reduce the risks of the surgery.

20. Claim 9 rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965, as applied to Claim 5, and in further view of Ablaza (US Patent 4,632,113).

21. Claim 9: SU'696 and Phillips'965 teach the limitations of Claim 9, except for the use of suture pads.

22. Ablaza'113 teaches the use of suture pads (12 in Figure 1, or 20 in Figure 2) attached to suture strands (18) because they prevent any movement between the suture and the pad, and reduce the tendency of the suture to tangle; further, Ablaza'113 teaches that suture pads are used as anchors when the suturing device is used to close a slit in an aorta (column 2, lines 63-68 and column 3, lines 1-8). Therefore it would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by SU'696 and Phillips'965 with a suture pad because they allow the suture to act as an anchor when closing the aorta.

23. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965, as applied to Claim 5, and in further view of Alpern, et al. (US Patent 5,284,293).

24. SU'696 and Phillips'965 teach the limitations of Claim 12, except for the use of a package for housing the suture device. Alpern'293 teaches that it is well known in the art to use a dispenser to house suturing devices prior to use because they are packaged in a sterile manner and it is beneficial to be able to see the quantity of suturing devices in a box (column 1, lines 1-34). Therefore it would have been obvious to one skilled in the art at the time the invention was made to place sterile packaged

sutures in a box prior to use because this makes it easier for doctors to see the quantity of suturing devices in the box.

25. Claim 13 rejected under 35 U.S.C. 103(a) as being unpatentable over SU'696 and Phillips'965, as applied to Claim 5, and in further view of Ovil, et al. (US Patent 4,702,250).

26. SU'696 and Phillips'965 teach the limitations of Claim 13, except for a mechanical suture placement device.

27. Mechanical suture placement devices are well known in the art and it would have been obvious to include a mechanical suture placement device to place the sutures. Furthermore, Ovil'250 teaches the use of a mechanical suture placement apparatus because suture placement is time consuming and there is a risk of entangling the sutures. Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a mechanical suture placement device to place the sutures because it is easier for the surgeon and reduces the risk of entanglement.

Response to Arguments

28. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lb

(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER
8/2/07